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A randomised controlled trial of trans-anal versus trans-vaginal repair for symptomatic anterior rectocoele

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/09/2013	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0050166862

Study information

Scientific Title

Study objectives
A rectocoele is a common problem caused by weakness in the tissues of the pelvis, which leads to problems with defecation. A number of surgical approaches to repair of a rectocoele are available. Currently in our institution a patient will have rectocoele repair either through the anus or through the vagina. No consensus of opinion exists as to which is the superior approach. The aim of this study is to randomise the patients to one or the other operation to establish which approach is superior.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Rectocoele

Interventions
Patients will be selected from the clinics for suitability for surgical repair of their rectocoele following appropriate investigations. All patients will be assessed in a structure manner. A specific questionnaire will be filled in by the patient preoperatively. This questionnaire includes SF-36v2 global quality of life assessment tool, the Cleveland continence scoring toll and specific questions on defecation habits, and dyspareunia.

The presence of a symptomatic rectocele in the absence of other pathology renders the patient suitable for inclusion into the trial and after providing adequate information and fully informed

consent they will be randomised to transanal or transvaginal repair. This would happen preoperatively to allow the patient to be counselled and consented about the exact procedure they will undergo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Functional outcome and quality of life changes by the surgery.

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/06/2005

Completion date
01/02/2006

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Research participants will be recruited from the outpatient clinic once they have been identified by preoperative investigation to be suitable for surgical repair of their rectocoele. Inclusion criteria:
1. The presence of excessive straining, incomplete evacuation
2. The requirement for perineal/vaginal digital pressure during defecation
3. Vaginal bulging and constipation, due to a rectocoele as proven on defaecography, in the presence of a normal large bowel.
These are standard indications for rectocoele repair.

62 patients will be recruited in to the study from the department of Colorectal Surgery and Gynaecology, 31 patients will be in each arm.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants

Key exclusion criteria
Patients with a slow transit colon or sphincter defects as these patients have been shown not to benefit from rectocoele repair.

Date of first enrolment
02/06/2005

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Royal Infirmary
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust (UK) Own Account

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration